MIT I 9 200 BY THINK

03/10/04

Application Serial Number

09/621,268

1642\$

RADEMARK	Filing Date	July 21, 2000	
	First Named Inventor	Gillies	
ΓRANSMITTAL	Group Art Unit	1642	
FORM	Examiner Name	K. Canella, Ph.D.	
	Attamay Docket No.	LEY-007	

		EN	NCLOSURES (ch	eck all that apply)		
⊠ Fee	Transmittal Form		Copy of Notice to Parts of Applicat			Appeal Communication to Board of Appeals and Interferences
	☐ Check Attached ☐ Copy of Fee Transmittal Form		Formal Drawing	(s)		Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
	Amendment/Response		Petition Routing and Accompany	Slip (PTO/SB/69)		Status Letter
	☐ After Final ☐ Affidavits/declaration(s)		To Convert to a		⊠	Return Receipt Postcard
	Letter to Official Draftsperson		Application			Certificate of First Class Mailing under 37 C.F.R. 1.8
	including Drawings [Total Sheets]		Power of Attorna (Revocation of F			Additional Enclosure(s) (please identify below)
	Extension of Time Request		Terminal Discla	mer		v ,
⊠	Third Supplemental Information Disclosure Statement		Executed Declaration and Power Attorney for Utility or Design Patent Application			
\boxtimes	Form PTO-1449					
⊠	Copies of Third SIDS Citations (A75-A91; B105; and C180-C235)		Small Entity Sta	tement ·		0
	Certified Copy of Priority Document(s)		Request for Ref	und		
			After Allowanes	Communication	-	
	Response to Missing Parts/ Incomplete Application		ю огоар			٠
CORRI	ESPONDENCE ADDRESS	_		SIGNATURE BL	OCK	
		Administra	itor			Respectfully submitted,
	Testa, F High St 125 Hig Boston, Tel. No	Iurwitz & reet Towe th Street MA 021 .: (617) 24 : (617) 24	10 18-7000	Date: March 9, 200 Reg. No. 48,645 Tel. No.: (617) 248 Fax No.: (617) 248	3-7697	Brian A. Fairchild, Ph.D. Attorney for Applicant(s) Testa, Hurwitz & Thibeault, LLP High Street Tower 125 High Street Boston, MA 02110

FEE TRANSPITTAL FY 2003 MAR 0 9 2004

		Complete if Known	
Į	Application Serial Number	09/621,268	
	Filing Date	July 21, 2000	
١	First Named Inventor	Gillies	
	Group Art Unit	1642	
	Examiner Name	K. Canella, Ph.D.	
	Attorney Docket No.	LEX-007	

METHOD OF PAYMENT	FEE CALCULATION (continued)				
1. Payment Enclosed:	3. ADDIT	IONAL FE			
Money Order Other	Large	Small			
_	Entity	Entity			
2. The Commissioner is hereby authorized to credit	Fee	Fee	Fee Description	Fee Paid	
or charge any fee indicated below for this submission	(\$)	(\$)			
to Deposit Account No. 20-0531.					
Required Fees (copy of this sheet enclosed).	130	65	Surcharge - late filing fee or oath		
Additional fee required under 37 CFR 1.16 and	50	25	Surcharge - late provisional filing fee		
1,17.			or cover sheet		
Overpayment Credit.	130	130	Non-English specification		
3. Applicant claims small entity status.	2,520	2,520	Request for ex parte reexamination		
FEE CALCULATION	110	55	Extension for reply within first month	<u> </u>	
1. FILING FEE	410	205	Extension for reply within second month		
Large Entity	930	465	Extension for reply within third month		
Fee (\$) Fee Description Fee Paid	1450	725	Extension for reply within fourth month		
•	1970	985	Extension for reply within fifth month		
750 Utility filing fee	320	160	Notice of Appeal		
330 Design filing fee	320	160	Filing a brief in support of an appeal		
160 Provisional filing fee	280	140	Request for oral hearing		
•	130	130	Petitions to the Commissioner	100.00	
	180	180	Submission of Information Disclosure	180.00	
Number Number Rate Amount Filed Extra	750	375	Statement Filing a submission after final		
Piled Extra			rejection (37 CFR 1.129(a))		
Total Claims $-20 = x \$ 18.00 =$	750	375	For each additional invention to be examined (37 CFR 1.129(b))		
Independent Claims - 3 = x \$ 84.00 =	100	100	Certificate of Correction for applicant's error		
Claims - 3 = x \$ 84.00 =	Other fee (S	necify)	аррисши з спог		
☐ Multiple Dependent Claim(s), if any \$280.00 =	Other fee (S				
TOTAL:					
SMALL ENTITY DISCOUNT:	1				
SUBTOTAL (1) (\$) 0.00					
2. AMENDMENT CLAIM FEES			SUBTOTAL (3)	3) 180.00	
Claims Highest No. Present Rate Fee Paid			SUBTOTAL (3)	180.00	
Remaining Previously Extra After Amend, Paid For	<u> </u>				
				r	
Total - = $x \$ 18.00 = 0.00$			SUBTOTAL (1)		
Indep = x \$ 84.00 = 0.00			SUBTOTAL (2) SUBTOTAL (3)		
First Presentation of Multiple Dep. + \$280.00 =			30D101AL (3)	1.00.00	
Claim TOTAL: (\$) 0.00	1				
SMALL ENTITY DISCOUNT: (\$)					
SUBTOTAL (2) (\$) 0.00	1		TOTAL (\$)	180.00	
CORRESPONDENCE ADDRESS			SIGNATURE BLOCK		
Direct all correspondence to:			Respectfully submitted		
Patent Administrator	Date: Marc	h 9 2004	Bi mill		
Testa, Hurwitz & Thibeault, LLP	Reg. No.: 4		Brian A. Fairchild, Ph.D.		
High Street Tower-125 High Street		517) 248-76			
Boston, MA 02110		617) 248-71	*		
Tel. No.: (617) 248-7000	,	, =	High Street Tower-125 High		
Fax No.: (617) 248-7100			Boston, MA 02110		
2020087 1					



PATENT Attorney Docket No. LEX-007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Gillies et al.

SERIAL NO.: 09/621,268

GROUP NO .:

1642

FILING DATE:

July 21, 2000

EXAMINER:

K. Canella, Ph.D.

TITLE:

Fc Fusion Proteins for Enhancing the Immunogenicity of Protein and Peptide Antigens

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

	(1)	within three (3) months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the first Office action on the merits, or before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. 1.114; or	D VO
\boxtimes	(2)	after the period defined in (1) but before the mailing date of a final action or a notice of allowance under 37 C.F.R. 1.311, and	
		the requisite Statement is below, OR	

Third Supplemental Information Disclosure Statement Atty Docket No. LEX-007 Serial No. 09/621,268 Page 2 of 2

	\boxtimes	the requisite fee under 37 C.F.R. 1.17(p), namely \$180.00, is included herein, or
	(3)	after the mailing date of a final action or notice of allowance but before the payment of the issue fee, AND
		the requisite Statement is below, AND
		the requisite petition fee under 37 C.F.R. 1.17(p), namely \$180.00 is included herein.
	-	fully requested that each of the patents and publications listed on the attached Form ther information contained herein, be made of record in this application.
F	Applicants	believe no additional fee is required for entry and consideration of this paper. If an
additio	onal fee is	required, please charge Deposit Account 20-0531.

Respectfully submitted,

Date: March 9, 2004

Reg. No. 48,645 Tel. No.: (617) 248-7697

Fax No.: (617) 248-7100

3030991_1

Brian A. Fairchild, Ph.D. Attorney for Applicants

Testa, Hurwitz & Thibeault, LLP

125 High Street

Boston, Massachusetts 02110

FORM PTO - 1449

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-007

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/621,268

			BRUEN	ATENT	DOCUMEN	NTS				
EXAM. INIT.		DOCUMENT NUMBER	DATE		FILING DA' DOCUMEN		CLASS	SUB CLAS		G DATE IF OPRIATE
	A75	4,703,008	10/27/87		Lin					
	A76	5,441,868	8/15/95		Lin					
	A77	5,457,038	10/10/95		Trinchieri et a	ıl.				
	A78	5,547,933	8/20/96		Lin					
	A79	5,618,698	4/8/97		Lin					
	A80	5,688,679	11/18/97		Powell	ĺ				
	A81	5,756,349	5/26/98		Lin					
_	A82	5,955,422	9/21/99		Lin					
	A83	6,231,536	5/15/01		Lentz					
	A84	6,284,536	9/4/01		Morrison et a	ł.				
-	A85	6,340,742	1/22/02		Burg et al.					
	A86	6,506,405	1/14/03		Desai et al.					
	A87	6,583,272	6/24/03		Bailon					
	A88	6,586,398	7/1/03		Kinstler et al.					
	A89	2002/0142374	10/3/02		Gallo et al.					
	A90	2003/0003529	1/2/03		Bayer					
	A91	2003/0012789	1/6/03		Blumberg et	al.				
			FOREIG	JN PATE	NT DOCU	MENTS				
EXAM INIT.		DOCUMENT NUMBER	DATE	COUNTR	CLASS	SUB CLASS	FILIN		ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B105	WO 00/24893	5/4/00	РСТ						
EXAM. INIT.	отні	ER DOCUMENTS:	(Including A	Author, Tit	e, Date, Relev	vant Page	s, Place	of Publ	lication)	
	C180	Becker et al., (1996) Therapy," J Clin Inv			erable Tumor	Immunit	y in Mice	after T	argeted Inter	leukin-2
	C181	Becker et al., (1996) Interleukin-2 Therap	y," <u>J Exp. M</u>	<u>1ed.</u> , 183(50):2361-6.					
	C182	Briggs et al., (1974), Physiology, 227(6):		learance of	ntact and desi	alylated E	Erythropo	ietin," <u>/</u>	American Jo	urnal of
EXAMI	VER				DATE CON	SIDERE	D			

FO	RM	PTO-	1449

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-007

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/621,268

		9	MAR 0 8 2004 (5)	SERIAL NO.: 09/6 FILING DATE: Ju		0 GRO	OUP: 1642				
			COULS, RASPEN	DOCUMENTS	., 21, 200						
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE				
	C183	Chuang et al., (1994 Anticancer Drug Tax	g et al., (1994), "Alteration of Lymphocyte Microtubule Assembly, Cytotoxicity, and Activation by the cer Drug Taxol," Cancer Research, 54:1286-1291.								
	C184	Cruse et al., (1995),	Illustrated Dictionary	of Immunology, CRC P	ress, NY, p	.156-7.					
	C185	Davis et al., (2003), Immunother., 52:29		mplification of Anti-ca	ncer Immur	ity," <u>Cance</u>	r Immunol.				
	C186			man Prostate Carcinom munocytokine Therapy							
	C187	Duncan et al., (1988), "The Binding Site for C1q on IgG," Nature, 332:738-740.									
	C188		"Development and Ch Dial. Transplant., 16:3-	aracterization of Novel -13.	Erythropoi	esis Stimula	ating Protein				
	C189	Elliott et al., (1997), "Mapping of the Active Site of Recombinant Human Erythropoietin," <u>Blood</u> , 89(2):493-502.									
C190 Frost et al., (1997), "A Phase I/IB Trial of Murine Monoclonal Anti GD2 Antibody 14.G2a in Children with Refractory Neutroblastoma," Cancer, 80:317-33.						2a Plus Interleukin-2					
	C191	Fusion Proteins," Clin. Diagn. Lab. Immunol., 6(2):236-42.									
	C192										
	C193			tine Fusion Proteins for mmunother, 51(8):449		py and An	tibody-targeted				
	C194			ng Half-life and eRffica cellular Proteolysis," <u>Cl</u>							
	C195	1), Neuronal Properties A, 72(12):4923-4927.	of Hybrid Neuroblasto	ma X Symp	athetic Gar	glion Cells," Proc.				
	C196			n Effector Cells by a Tu 8-IL2)," Clin Cancer R			nant Anti-ganglioside				
	C197			ak serum levels and imr nocytokine," Methods N			umanized anti-				
	C198			othase Gene by Express ody," Proc. Natl. Acad.							
	C199		ocessing of C-terminal promatogr. A., 705:129	Lysine and Arginine R 9-134.	esidues of I	roteins Iso	lated from Mammalian				
	C200			Activities of a Panel of Type 1," <u>J. Virol.,</u> 75(2			Neutralizing Antibody				
EXAMI	NER	1	-	DATE CONSIDI	ERED						

FO	RM	PTO	- 1	449

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-007

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/621,268

			E E	ENT I	OCUMENTS			_			
EXAM. INIT.		DOCUMENT NUMBER	DATE		AME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE			
•	C201	C201 Idusogie et al., (2000), "Mapping of the C1q Binding Site on Rituxan, a Chimeric Antibody with a Human IgG1 Fc," J. Immunol., 164(8):4178-4184.									
	C202	Antitumor Effector	Mechanism of Im	munocy	class I Expression on tokine Therapy," <u>Ca</u>	ncer Res., 6	1(4):1500-	7.			
	C203	Kato et al., (1997) of Pharmacology a	"Mechanism for t and Experimental T	he Nonli herapeu	near Pharmacokinet tics, 283:520-527.	ics of Eryth	ropoletin in	Rats," The Journal			
	C204	Kato et al., (1998) Disposition, 26:12		s of Eryt	thopoietin in Genetic	ally Anemi	c Mice," <u>D</u>	rug Metabolism and			
	C205	for Neuroblastoma	," J. Clin, Oncol.,	19:4189							
	C206	Marrow," J Natl C	ancer Inst., 89(21)	:1586-94				etastases to Bone			
	C207	Lode et al., (2000)	, "What to do with	Targete	d IL-2," <u>Drugs Toda</u>	<u>y</u> , 36(5):32	1-36.				
	C208	by CD40/CD40L	Interaction," J. Clin	n. Invest	<u>.</u> , 105(11):1623-30.			-cell Help Mediated			
	C209	Macdougall, (2002), "Optimizing the Use of Erythropoietic Agents—Pharmacokinetic and Pharmacodynam Considerations," Nephrol. Dial. Transplant., 17:66-70.									
	C210	Protein Facilitates	Neutrophil Antibo	ody-depe	ide/granulocyte Mac indent Cellular Cytot r Cell Adhesion and	oxicity and	Depends o	ating Factor Ffusion in FcyRII (CD32) and ocytosis," <u>Blood</u> ,			
	C211	Mueller et al. (199 Constant Regions 34(6):441-452.	97), "Humanized P Block Human Leu	orcine V kocyte E	CAM-specific Mon- Binding to Porcine E	oclonal Ant ndothelial (ibodies with Cells," <u>Mol</u> e	h Chimeric IgG2/G4 ecular Immunology,			
	C212	Mullins et al. (19) of Antitumor Act	97), "Taxol-mediat ivities," <u>Cancer Im</u>	ed Chan munol. I	ges in Fibrosarcoma mmunother, 45:20-2	induced Im	mune Cell	Function: Modulation			
	C213	Naramura et al., " Protein against H	Mechanisms of Ce uman Melanoma C	ellular Cy ells," <u>Im</u>	ytotoxicity Mediated imunology Letters, 3	by a Recor 9(1):91-9.	nbinant An	tibody-IL2 Fusion			
	C214	Neal et al. (2003) Recurrence Follo	, "NXS2 Murine N wing NK-depender	leuroblas nt Immu	stomas Express Incre notherapy," Cancer I	ased Levels mmunol Im	of MHC Communother.,	Class I Antigens upon 53:41-52.			
	C215	Ngo et al., (1994) 495, Birkhauser I		ding Pro	blem and Tertiary St	ructure Pre	diction," pp	. 433-440 and 492-			
	C216	Niethammer et al Growth and Diss	., (2002) "An oral emination of Lewis	DNA Va s Lung C	accine against Huma arcinoma in CEA Ti	n Carcinoer ansgenic M	nbryonic A lice," <u>Vacc</u> i	ntigen (CEA) Prevents ine, 20:421-9.			
EXAM	INER	<u> </u>			DATE CONSIDI	ERED					

FORM PTO - 1449

THIRD SUPPLEMENTAL INFORMATION ODISCLOSURE STATEMENT MAR 0 4 2000

ATTORNEY DOCKET NO.: LEX-007

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/621,268

FILING DATE: July 21, 2000 GROUP: 1642

PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE				
	C217	 Niethammer et al., (2001) "Targeted Interleukin 2 Therapy Enhances Protective Immunity Induced by an Autologous Oral DNA Vaccine against Murine Melanoma," <u>Cancer Research</u>, 61(16):6178-84. Nimtz et al., (1993) Structures of Sialylated Oligosaccharides of Human Erythropoietin Expressed in Recombinant BHK-21 Cells," <u>Eur. J. Biochem.</u>, 213:39-56. 									
	C218										
	C219	Severe Combined Im 42(2):88-92.	munodeficiency by A	ablished Hepatic Huma Antibody-targeted Interle	eukin-2," <u>C</u>	incer minu	mor, minumomer.,				
	C220	Biotechnol, Appl. Bi	ochem., 32:167-172.	er and Cell line in High-							
	C221	Lab Anal., 10(3):160)-6.	kin 2 Fusion Proteins: A							
_	C222	Melanoma Metastas 56(8):1707-12.	es in Athymic nu/nu	Lymphocytes in the Gr Mice by an Antibody-ly	mphotoxin	rusion Proi	eili, <u>Cancer Res.,</u>				
	C223	Fusion Protein to Ss 61(23):8498-503.	uppress Growth and	9) Chemokine Gene The Dissemination of Murin	e Colon Ca	стопа, с	cancer Res.,				
	C224	Hepatic Human Sev	ere Combined Immu	nodeficiency Mice," Pro	Fusion Protein Suppresses Growth of c. Natl. Acad. Sci. USA, 91(20):9626-30.						
	C225	Review and Meta-a	(2001), "Epoietin Treatment of Anemia Associated with Cancer Therapy: A Systematic -analyis of controlled Clinical Trials," <u>Journal of National Cancer Institute</u> , 93:1204-1214.								
	C220	Acetylglucosamine Antibody-depender	of Human IgG1 Con at Cellular Cytotooxid	f Fucose but Not the Pre pplex-type Oligosaccharisty," J. Biol. Chem., 278	ides Shows 3:3466-347	the Critical	Role of Enhancing				
	C22	Strom et al., (1996), "Therapeutic Approach to Organ Transplantation," <u>Therapeutic Immunology</u> , Blackwell Science, Chapter 36, pp. 451-456.									
	C22	8 Thommesen et al., Complement Activ	(2000), "Lysine 322 ation," <u>Mol. Immuno</u>	in the Human IgG3 CH2 1., 37(16):995-1004.	Domain is	Crucial for	Antibody Dependent				
	C22	9 Wells, (1990), "Ad	ditivity of Mutationa	Effect in Proteins," Bio	chemistry,	29(37):850	9-8517.				
	C230 Xiang et al., (1998), "Induction of Persistent Tumor-protective Immunity in Mice Cured of Establi Carcinoma Metastases," Cancer Research, 58(17)3918-3925.										
	C23	Immunol., 163(7):	3676-83.	ainst Colon Carcinoma i	_						
	C23	Trimer induces T	Xiang et al., (2001), "A Dual Function DNA Vaccine Encoding Carcinoembryonic Antigen and CD40 Ligan Trimer induces T Cell-mediated Protective Immunity Against Colon Cancer in Carcinoembryonic Antigen-Transgenic Mice," <u>1 Immunol.</u> , 167(8):4560-5.								
EXAN	IINER	_L		DATE CONSID	ERED		<u> </u>				

FORM PTO - 1449

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-007

APPLICANT(S): Gillies et al.

SERIAL NO.: 09/621,268

FILING DATE: July 21, 2000 GROUP: 1642

U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	C233	Oral DNA Vaccine in CEA-transgenic Mice," Clin Cancer Res., 7(3 Supp):S856-S864.					
	C234	ch14.18 in Patients with Refractory Neuroblastoma and Osteosarcoma," J. Clin. Oncol., 16(6):2169-80.					
	C235	Zagozdzon et al. (1999), "Potentiation of Antitumor Effect of IL-12 in Combination with Paclitaxel in Murine Melanoma Model In Vivo," International Journal of Molecular Medicine , 4:645-648.					

EXAMINER

DATE CONSIDERED

3030550_1